

# THE EVALUATION OF OVULEN 50 Mcg. AS ORAL CONTRACEPTIVE

by

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The Indian Government has made it mandatory that recommendations of the Dunlop Committee should be followed and oral contraceptive pills must have low oestrogen-less than 0.1 mg in their formula. Following this a number of new contraceptive preparations containing low oestrogen have been introduced. Ovulen 50 is a combination pill containing 1 mg. of ethynodiol diacetate and .05 mg. of Mestranol. It was felt that necessary to study the effect of this preparation as oral contraceptive and on general health for assessing long term safety.

## *Material and Methods*

The trial is based on experience of 2500 cycles of 235 participants. These women essentially belonged to low economic strata. Most of them were between 20-30 years of age and had less than Rs. 200/- per capita monthly income. Only eight women had taken college education. Most of them had used some contraceptive method before (Table I-VI). Seventy-five women were directly switched from a preparation containing high oestrogen which they had taken for some time.

The volunteers were examined thoroughly. History of previous diseases

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was carefully asked and when found suitable were asked to start the course from day 5 of menstrual cycle. They were asked to come every month to secure their quota of pills. Records of routine complaints and investigations such as blood pressure body weight, vaginal smears, etc. were kept and problem cases were referred to various specialists and treated.

## *Adverse Reactions*

Table VII gives the adverse reactions suffered by the women while on the pills. The important ones are giddiness. Menstrual complaints and thrombophlebitis.

## *Giddiness*

Seventeen women complained of giddiness in the last cycle. It is a complaint mostly due to under-nourished state of the patient. However, after the 1st cycle only a few women repeated the complaint.

## *Effect on Menstruation*

In almost all the women the cycle became very regular. The major menstrual complaints were breakthrough bleeding, delayed period, scanty flow.

## *Breakthrough Bleeding*

There were total 68 cycles of breakthrough bleeding in different patients. Out of these only 9 women stopped tak-

TABLE I  
From 1st August 1970 to June, 1972

Ovulen 50 meg.			No. of cycles 2505
No. of women 235			
Continued women 87	Drop outs 148	Total 235	
Cycles continued women 1691		Cycles drop outs 814	Total cycles 2505

TABLE II

## Age

(Continued women)	Below 20	20-30	31-40	Above	Total
	1	57	29		87
(Drop outs)	1	124	23	—	148

TABLE III

## Per Capita Monthly Income

(Continued)	Below 50	50-100	101-200	Above 200	Total
	35	30	18	4	87
(Drop outs)	60	60	27	1	148

TABLE IV

## No. of Living Children

(Continued)	Nil	1-4	Above	Total
	2	78	7	87
(Drop outs)	1	136	11	148

TABLE V

## Education

(Continued)	No. School	Primary School	Middle High School	+ SSC. Col.	Total
	14	32	33	8	87
(Drop outs)	32	55	65	6	148

TABLE VI

## Contraceptive Used Before

(Continued)	Nil	Contraceptive D + Jelly	Used before condom	O.C.	IUCD	Total	
	49	8	9	21	10	87	
(Drop outs)	Safe period 861	Nil 86	O.C. D + Jelly 28	Condom 7	IUCD 18	Induced abor. 21	Total 3
						148	



TABLE VII  
Ovulen 50 Side Reactions (Cyclewise)

	1st Cycle 235	2nd cycle to 4th cycle	5th to 10th cycle 1746
Nausea	8	—	1
Breakthrough bleeding	17	22	29
Swelling on legs	—	—	2
Less milk	—	1	1

ing the pills for this reason. The bleeding was controlled by doubling the dose in the rest of the cases.

#### Delayed Periods

Seven women complained of delayed periods. Only one got it on more than one occasion. The women were asked to start the second course of pill after a gap of seven days, if period was delayed. Regular cycles were restored in all the women.

#### Venous Thrombosis

This was found in two women. The first patient had taken two types of preparations—Enavid 2.5 mg. and ovulen 1 mg. for 44 cycles, before she was switched on to ovulen 50. This was her 4th cycle on ovulen 50. She complained of oedema and pain in left leg. The physician diagnosed local venous thrombosis and advised discontinuation of the pills. The complaints disappeared with usual measures. The second patient also was switched from previous oral contraceptives to ovulen 50. She had oedema on right arm and forearm and she was advised to stop the pills. The oedema subsided but recurred twice. She finally got completely cured.

#### Effect on Lactation

Out of total 235 women, only 42 were giving breast feeds to the babies. Only

two of them complained of diminished lactation. But they did not discontinue the pills.

#### Cervical dysplasia

Repeated cytological check ups of cervical secretions were done. In one case cervical dysplasia was discovered. Hysterectomy was done in her case. On histopathological sectioning the uterus, no evidence of malignancy was detected in the cervix.

Ten patients were asked to discontinue the pills because they had medical conditions Jaundice (3), Thrombosis (2), haemoptysis (1), Convulsions (1) Burning of micturition (2), Cervical dysplasia (1) (Table VIII).

#### Symptoms in the First Cycle

These were compared with those occurring with other oral contraceptive preparations such as:

1. Ovulen 1 mg. Ethynoidiol diacetate 1 mg. Mestranol 0.1 mg.
2. Serial 28 Megestrol acetate 1 mg. +Ethynil estradiol 0.1 mg. sequential
3. Volidan 1 mgm. Ethynil estradiol Megestral Acetate 1 mg. combination
4. Megestrol acetate continuous low dose progesteron 0.4 mgm.

Out of these two were combination pills, one was sequential and one continuous progesterone pill. In comparison with all these preparations, the in-

TABLE VIII

*Dropouts Due to Adverse Symptoms*

Causes	Number
Nausea	1
Giddiness	7
Weakness	12
Jaundice	3
Rash	3
Thrombophlebitis	2
Piles	1
Constipation	1
Breakthrough bleeding	9
Failure	1
Haemoptysis	1
Convulsions	1
Burning all over the body	2
Petechial haemorrhages on skin	1
Itching vulva	1
Scanty urine	1
Pain in abdomen	1
Oedema of legs	1
Cervical dysplasia	1
Total	50

incidence of nausea, vomiting, giddiness was less with ovulen 50. However, the incidence of breakthrough bleeding was more with ovulen 50. (Table IX)

*Clinical Efficacy*

The preparation is most effective as far as contraceptive action is concerned. There was one pregnancy in this series.

The pregnancy rate was  $(\frac{1}{2500} \times 12)$

0.5 per hundred women years when the women followed the method regularly

*Causes of Dropouts*

In the course of two year, 148 women discontinued the pills for various reasons: Ninety-eight women discontinued for reasons not related to the method. Forty-nine patients did not turn up and 15 patients had gone out of town. Eleven patients had planned to have further pregnancy, while two became pregnant because they were irregular. Three patients had tubectomy done and one patient's husband got vasectomised. Four women changed temporarily to other contraceptives, 2 discontinued due to family doctor's advise. Other dropouts were for some minor reasons. (Table X)

TABLE IX

*Comparison of the Symptoms of the Various Oral Contraceptives*

	Nausea	Vomit- ing	Break- through bleed- ing	Giddi- ness	Weak- ness	Throm- bosis
Ovulen 1 mgm.	3.3%	0.4%	5%	6.7%	2.5%	—
Ovulen 50	3.4%	.8%	7.2%	5.1%	2.5%	.8%
Megestral Acetate 1 mgm. + Ethynil oestra- diol 0.1 mgm. (Sequen- tial)	4.3%	4.3%	.1%	8.6%	1%	—
Megestral Acetate 1 mgm. + Ethynil oes- tradiol 0.1 mgm. (Voli- dan combination)	4.7%	3.8%	4.7%	6.6%	2.8%	—
Meg. Acetate 0.4 mgm.	5.4%	—	17%	1.3%	1.3%	—



TABLE X

## Dropouts Due to Causes Not Related to Method

Did not turn up	49
Gone out of Bombay	15
Death or illness of child	3
Unsuitable clinic time	2
Planned pregnancies	11
Unplanned pregnancies	2
Sterilisation operation done	3
Husband disapproved	2
Family doctor's advise	2
Temporarily changed to other method	4
Unknown	3
Mislanecous	2
<b>Total</b>	<b>98</b>

## Summary

Ovulen 50 is a low oestrogenic oral contraceptive. This study shows that it is an effective and well accepted contraceptive. The adverse reactions and causes of dropouts did not substantially differ from other oral contraceptive preparations.

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